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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jian Cao

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EXAMINER

BERTRAM, ERIC D

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,512	Applicant(s) CAO ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10, 16-19 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-19 and 21-26 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/2008 entered.
2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
3. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Response to Arguments

4. Applicant's arguments filed 10/9/2008 have been fully considered but they are not persuasive. The applicant argues first that Koyrakh does not disclose that the plurality of beats need to be consecutive. The Examiner agrees. However, Koyrakh does meet the limitation of "determining whether there are first consecutive events of the plurality of events having first characteristics." Specifically, Koyrakh discloses sensing a plurality of ventricular sensed events that are then stored in random access memory 526 (par. 0045). Each event is then analyzed to determine whether the events have an RR interval greater than 600ms. If the event has a RR interval less than 600ms, the next event will then be evaluated. If the next (i.e., consecutive) event also has an RR interval less than 600ms, then the next event will be evaluated (par. 0046). In other words, if the events are consecutive, Koyrakh will inherently determine that the events had RR intervals less than 600 ms, and thus meets the limitation.

5. The applicant further argues that Koyrakh does not disclose that the beats with second characteristics are taken subsequent to the not-normal beats. In response, the Examiner concedes that Koyrakh does not disclose that the beats with second characteristics are **always** taken subsequent to the not-normal beats. However, Koyrakh does disclose that after detecting the plurality of events having first characteristics and then identifying a normal beat, a determination is made as to whether six normal beats have been collected, and, if not, the process continues until six normal beats have been collected. If the detected normal beat was the first beat

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detected, then that, and the next five normal beats, will have been collected subsequent to the first consecutive beats.

6. As an example, say the process shown in figure 4 was initiated, and the beats went in this order: not-normal, not-normal, normal, normal, normal, normal, normal, normal. In this scenario, Koyrakh teaches that the first consecutive events will be determined to have first characteristics (e.g., an RR interval less than 600 ms), and then subsequent to the first consecutive events, the 6 events will be determined to be normal. Clearly, the method of Koyrakh inherently reads on the claim.

7. The 35 USC 102(b) and 103(a) rejections of claims 1-4, 6-10 and 27-34 are still considered proper.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 6-10, and 27-29 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Koyrakh et al. (US 2002/0087091, hereinafter Koyrakh). Koyrakh discloses a method for generating a template in an implantable medical device (IMD).

10. Regarding claims 1, 3, 9, 27, 29, 31 and 33, Koyrakh discloses sensing a plurality of ventricular sensed events that are then stored in random access memory 526 (par. 0045). Each event is then analyzed to determine whether the events have an RR interval greater than 600ms. If the event has a RR interval less than 600ms, the

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next event will then be evaluated. If the next (i.e., consecutive) event also has an RR interval less than 600ms, then the next event will be evaluated (par. 0046). Koyrakh discloses that the events will continue to be evaluated until 6 events are found to have RR intervals greater than 600ms (i.e., a rate greater than and is not a paced event. These 6 selected events will then be used to generate a template (par. 0047). A plurality of cross-matches are then generated between the selected events by matching the first beat against the second through sixth beats to generate five cross-matches. If at least 4 of the 5 cross-matches are within a predetermined threshold, then a template is generated from the cross-matches that meet the threshold by averaging the cross-matches to create an average R wave snapshot (par. 0047).

11. Regarding claims 2, 8, 28 and 32, the consecutive events will inherently have RR intervals greater than 0 ms.

12. Regarding claim 6, Koyrakh discloses that if 4 or more of the cross-matches do not meet the threshold, then a delay of a predetermined time period will occur before the procedure is repeated (par. 0047).

13. Regarding claim 7, if the template is determined to be invalid or inaccurate, then the template generation method is repeated, again using a plurality of sensed events in random access memory (par. 0045). Since this is the second time the method is performed, the examiner considers the consecutive events and selected events, as described above, to be "second."

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Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 3, 4, 29, 30, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koyrakh. Koyrakh discloses the essential features of the claimed invention including a sense event that is not a ventricular pace event and an event

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having an R-R interval greater than a predetermined rate of about 600 ms. Koyrakh does not disclose that sense events can comprise events other than those directly following a ventricular pace and sense events preceded by atrial paces by more than a threshold value. However, it is well known in the art that sensed events during or directly following an arrhythmia therapy are not representative of the natural electrical activity of the heart and should not be used as measurements representative of the natural electrical activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Koyrakh's invention by excluding events following a ventricular pace and sense events preceded by an atrial pace by less than a threshold duration of time to exclude beats that are not representative of the natural electrical activity of the heart.

18. Regarding claims 4, 30 and 34, the modified invention of Koyrakh discloses the claimed invention, but does not disclose expressly the AV threshold interval of 100 ms. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Koyrakh with the threshold interval of 100 ms because applicant has not disclosed that 100 ms provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been an obvious matter of design choice to modify Koyrakh's invention by using an AV threshold interval of 100 ms to obtain the invention as specified in the claims.

Allowable Subject Matter

19. Claims 16-19 and 21-26 are allowed.

Conclusion

20. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. D. B./
Examiner, Art Unit 3766

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
November 9, 2008